Cerebral Protection against Embolization during Thoracic EndoVascular Aortic Repair

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Disclosure

Speaker name:

R. Alexander Jánosi

I have the following potential conflicts of interest to report:

- [x] Consulting
- [ ] Employment in industry
- [ ] Stockholder of a healthcare company
- [ ] Owner of a healthcare company
- [ ] Other(s)

- [ ] I do not have any potential conflict of interest
Risk of stroke during TEVAR

• Like TAVI, TEVAR is prone to stroke due to the risk of dislodgement of debris
• Risk of clinically apparent, periprocedural stroke after TEVAR is about 1.9-5.8%
• Risk factors:
  o Prior stroke
  o Severe atheromatous disease involving aortic arch
  o TEVAR of proximal descending aorta has the highest perioperative stroke rate (espec. in comb. with prior stroke)
    ➢ Associated with a significant post-operative mortality

Risk of stroke during TEVAR

Silent brain infarcts increase the risk of clinical infarction by 2-4x in population based studies

- Associated with several adverse neurological and cognitive consequences:
  - Impaired mobility
  - Physical decline
  - Depression
  - Cognitive dysfunction
  - Dementia
  - Parkinson’s disease
  - Alzheimer disease

Example of a new focus of restricted diffusion (arrow) on postinterventional diffusion-weighted magnetic resonance imaging.
Claret Sentinel™ Cerebral Protection System (CPS)

- The 3rd generation of the first commercially available CE-marked embolic protection device
- Universal size and shape
- Deflectable compounded curve sheath to facilitate cannulation of LCC
- Ergonomically designed handle
The Claret Medical system is the ONLY embolic CAPTURE protection

<table>
<thead>
<tr>
<th>TriGuard™ Cerebral Protection Device</th>
<th>Edwards Embrella™ Embolic Deflector</th>
<th>Claret Sentinel™ Cerebral Protection System</th>
</tr>
</thead>
<tbody>
<tr>
<td>Deflector</td>
<td>Deflector</td>
<td>Filter capture</td>
</tr>
<tr>
<td>9F (femoral)</td>
<td>6F (radial)</td>
<td>6F (radial)</td>
</tr>
<tr>
<td>240 micron pore size</td>
<td>100 micron pore size</td>
<td>140 micron pore size</td>
</tr>
<tr>
<td>Aortic arch position</td>
<td>Aortic arch position</td>
<td>Brachiocephalic and LCC</td>
</tr>
<tr>
<td>CE marked</td>
<td>CE marked</td>
<td>CE marked and commercialized</td>
</tr>
</tbody>
</table>
Baseline characteristics

• 5 patients undergoing TEVAR deemed at high risk for periprocedural stroke
• Mean age 71.2 ± 7 years
• 2 male and 3 female
• 4 with aortic dissection type B
• 1 with thoracoabdominal aortic aneurysm
• 3 pts. with preoperative bypass of LSA
• cerebral protection using CPS
• Used Stent-grafts including
  • GORE TAG
  • Medtronic Valiant Captivia
Embolic debris captured during TEVAR procedures

- Five cases of TEVAR using Claret Cerebral Protection System.

- Subsequently analyzed by team of Dr Virmani at CVPath Institute
  - Debris includes acute thrombus, despite short procedures and high ACT, organized thrombus, artery tissue, and foreign material.
  - Debris characterization differs from TAVR, as expected, in lower rates of calcified debris.

<table>
<thead>
<tr>
<th>Type of Procedure, Center</th>
<th># of patients in series</th>
<th>Any debris</th>
<th>Acute Thrombus</th>
<th>Organizing Thrombus</th>
<th>Arterial Wall</th>
<th>Calcification</th>
<th>Foreign Material</th>
</tr>
</thead>
<tbody>
<tr>
<td>TEVAR, West-German Heart and Vascular Center Essen</td>
<td>n=5</td>
<td>100%</td>
<td>100%</td>
<td>70%</td>
<td>80%</td>
<td>10%</td>
<td>80%</td>
</tr>
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Note: percentages reflect percent of patients in the series in which each particular tissue type was captured. Some filters captured several types of debris, so percentages will not add to 100%
### Embolic debris captured during TEVAR procedures

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Debris captured by Claret Cerebral Protection Systems in various transcatheter procedure studies

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<th># of Patients in Series</th>
<th>Any Debris</th>
<th>Acute Thrombus</th>
<th>Organizing Thrombus</th>
<th>Valve or Artery Tissue</th>
<th>Calcification</th>
<th>Foreign Material</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>TAVR</strong>&lt;sup&gt;1&lt;/sup&gt;</td>
<td>n=40</td>
<td>75%</td>
<td>33%</td>
<td>20%</td>
<td>52%</td>
<td>20%</td>
<td>13%</td>
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<tr>
<td>Rotterdam - a variety of valves</td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td><strong>TAVR</strong>&lt;sup&gt;2&lt;/sup&gt;</td>
<td>n=30</td>
<td>100%</td>
<td>90%</td>
<td>87%</td>
<td>40%</td>
<td>20%</td>
<td>20%</td>
</tr>
<tr>
<td>Hamburg - a variety of valves</td>
<td></td>
<td></td>
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<td></td>
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<td></td>
</tr>
<tr>
<td><strong>TAVR</strong>&lt;sup&gt;3&lt;/sup&gt;</td>
<td>n=10</td>
<td>100%</td>
<td>50%</td>
<td>20%</td>
<td>40%</td>
<td>30%</td>
<td>0%</td>
</tr>
<tr>
<td>Hamburg - using Sapien 3</td>
<td></td>
<td></td>
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<td></td>
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<td></td>
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<tr>
<td><strong>TMVR</strong>&lt;sup&gt;4&lt;/sup&gt;</td>
<td>n=6</td>
<td>100%</td>
<td>83%</td>
<td>16%</td>
<td>50%</td>
<td>0%</td>
<td>100%</td>
</tr>
<tr>
<td>Aachen - using MitraClip</td>
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<tr>
<td><strong>TEVAR</strong>&lt;sup&gt;5&lt;/sup&gt;</td>
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3. St. Georg Hospital. CVPath report on file at Claret Medical (CLAME00579)
4. CVPath report on file at Claret Medical (MitraClip study)
5. Jánosi et al., presented at LINC 2016
Demonstration of in vivo plaque disruption

This case highlights the risk of performing TAVR/TEVAR in patients with atherosclerotic plaques.

Plotkin et al. Eur Heart J Cardiovasc Imaging 2013
Conclusions

The Cerebral Protection System, initially developed for TAVI, worked for all 5 TEVAR patients.

- Using a CPS during TEVAR is feasible and safe.
- Most prevalent types of debris were acute thrombus and foreign material consistent with hydrogel coating.
- Both were even more frequently than in TAVI procedures.

Larger studies are required to confirm our findings and to determine if embolic protection devices could reduce cerebral embolization during TEVAR.
Thank you for your attention!